



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,360	12/21/2001	Eugene H. Gans	01-40326-US	6447

7590

06/18/2003

William J. McNichol, Jr., Esquire
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/18/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,360

Applicant(s)

GANS ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 24-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant's election of Group I (claims 1-23) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-16 and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the claims are not ascertainable since it is not clear what is encompassed by the phrase "non-solvent/emulsifier"?

Claim 16 recites the limitation "non-solvent/emulsifier" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10, 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Poulsen (USPN 3,934,013).

Poulsen (USPN 3,934,013) discloses a topical pharmaceutical composition comprising a solvent base comprising 77.99% of propylene glycol/water and other excipients and adjuvants,

Art Unit: 1617

and two or more corticosteroids, e.g., fluocinolone acetonide, citric acid (0.01 g or 0.01%), Tween 60 (2 g or 2%), Span 60 (2.0 g or 2%), stearyl alcohol (15 g or 15%), and mineral oil (3.0 g or 3%), see in particular Example 2, col. 17, claim 1-15, and 27, compound B in particular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen (USPN 3,934,013).

Poulsen (USPN 3,934,013) discloses a topical pharmaceutical composition comprising a solvent base comprising 77.99% of propylene glycol/water and other excipients and adjuvants, and two or more corticosteroids (0.001-0.5%), e.g., fluocinolone acetonide, citric acid (0.01 g or 0.01%), Tween 60 (2 g or 2%), Span 60 (2.0 g or 2%), stearyl alcohol (15 g or 15%), and mineral oil (3.0 g or 3%), see in particular Example 2, col. 17, claim 1-15, and 27, compound B in

Art Unit: 1617

particular. Poulsen further teaches that the preferred weight percentage of water/glycol mixture of the base is between 70 and 95%, see col. 11, lines 44-60 for example.

Poulsen (USPN 3,934,013) does not teach some of the particular percentages of corticosteroid or propylene glycol herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ corticosteroid and propylene glycol in the particular weight percentages claimed herein.

One of ordinary skill in the art would have been motivated to employ corticosteroid and propylene glycol in the particular weight percentages claimed herein because ranges covering the instant weight percentages are taught to be useful in topical formulations by the prior art.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen (USPN 3,934,013) as applied to claims 1-7 and 10-19 above, and further in view of PDR entries of Lidex-Synalar.

Poulsen (USPN 3,934,013) does not teach the employment of a second penetration enhancer, neither does it teach the particular excipients herein as recited in claims 21-23.

PDR entries of Lidex-Synalar teaches the employment of propylene glycol and diisopropyl adipate together in a topical fluocinonide composition. PDR also teaches different excipients and adjuvants that can be employed in a topical fluocinonide composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any known pharmaceutical necessity in the amounts herein in a fluocinonide composition.

Art Unit: 1617

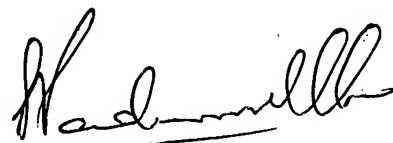
One of ordinary skill in the art would have been motivated to employ any known pharmaceutical necessity in the amounts herein in a fluocinonide composition because optimization of amounts is within the skill of the artisan and is therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
June 9, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

6/16/03